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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,844	08/25/2003	Subramaniam C. Krishnan	30909-1	3856
24256	7590	01/22/2008		
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER MALAMUD, DEBORAH LESLIE	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 01/22/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/648,844

Applicant(s)

KRISHNAN, SUBRAMANIAM C.

Examiner

Deborah Malamud

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18,21,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,21,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 23 November 2007 has been entered.

2. Claims 1-17, 19-20 and 22-35 are cancelled; claims 18, 21 and 36-37 are pending.

### ***Claim Objections***

3. In view of the amendments received 23 November 2007, the objection to claim 37 is withdrawn.

### ***Response to Arguments***

4. Applicant's arguments filed 23 November 2007 have been fully considered but they are not persuasive. The applicant argues, (page 6, "Remarks") "Independent [amended] claims 21 and 36 recite transseptal apparatuses which include a hollow sheath, a catheter and a recording device, wherein the catheter removably contacts the hollow sheath. However, Svenson et al [previously cited reference] fail to teach or suggest a transseptal apparatus having a catheter which removably contacts a hollow sheath. The Examiner contends that the

polymer sheath (24) disclosed in Svenson et al is a hollow sheath, however, this polymer sheath serves to capture the wires (21 a-21 c) of the device and seals the wires to secure them to a support tube (see col. 3, lines 67 - col. 4, line 9), and thus, is not removable. Therefore, the catheter of Svenson et al does not removably contact the polymer sheath (24), and as such, is not a hollow sheath as recited in independent claims 21 and 36." In response to applicant's argument that Svenson's catheter is not removable, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

***Claim Rejections - 35 USC § 102/103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 21 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Svenson et al (U.S. 5,409,008). Svenson discloses (col. 2, lines 30-36) "a mapping catheter which includes a polymer member, bipolar sensing electrodes placed on a distal end of said polymer member, a spaced unipolar electrode at a spaced distance from said bipolar electrodes, and a lumen within said polymer member for the passage of a laser catheter or other instrument." Svenson further discloses, (col. 3, lines 13-17) "a laser delivery catheter can be passed through the center hollow lumen

of the mapping catheter and the myocardium irradiated for a predetermined period of time to ablate the site." The examiner considers this to be a hollow lumen, a first electrode positioned on a distal end of the catheter, and a second electrode spaced proximally from the first electrode and positioned on the catheter. Svenson further discloses (col. 3, lines 53-64; Figure 1) "mapping catheter (10) including the catheter tip (12), the stainless steel support tube (14), the hand piece (16), and the Y-connector (18). The hand piece joins the Y-connector and the stainless steel support tube together and includes the electrical junction (20) of the wires (21a-21c) with electrical connectors (22a-22c), which in this example are insulated alligator clips. A polymer tube-like sheath (24) connects between the catheter tip (12) and the hand piece, and houses a plurality of wires (21a-21c) between the polymer sheath and the underlying stainless steel support tube." The examiner considers this to be a hollow sheath having a distal end. It is to be noted that the functional language and introductory statement of intended use of claims 21 and 36, have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Svenson utilizes a mapping catheter as claimed by the applicant, Svenson is therefore capable of being inserted into a sheath (such as polymer sheath 24), having a needle urged through, and being used as a dilator for performing a transseptal puncture and locating the fossa ovalis, on the basis of the claimed parameters. In addition nothing prevents the catheter of Svenson from being performing these functions. Therefore, they are capable of locating and penetrating the fossa ovalis and being used with a sheath and a needle.

7. Svenson further discloses, (col. 2, lines 56-62) "The current catheter provides a tool for more accurately mapping the electric potential of very small areas of the inner chambers of the heart. In addition, the catheter provides a way to simultaneously obtain the QRS and EKG signals, thus providing a method to more rapidly and accurately identify the focus or foci of the tachycardia." The examiner considers this system therefore inherently to include a recording device for recording electrograms, the recording device in electrical communication with the electrodes of the catheter. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a recording device for recording electrograms in order to display the data gathered by the electrodes for future diagnosis.

### ***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. Claims 18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svenson et al (U.S. 5,409,008). For a complete discussion of the claimed elements, please see above and the previous Final Office Action.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number

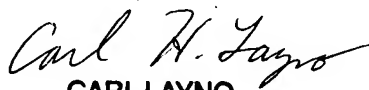
Application/Control Number:  
10/648,844  
Art Unit: 3766

Page 6

is (571) 272-2106. The examiner can normally be reached on Monday-Friday,  
9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the  
examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax  
phone number for the organization where this application or proceeding is  
assigned is 571-273-8300.

Information regarding the status of an application may be obtained from  
the Patent Application Information Retrieval (PAIR) system. Status information  
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free). If you would like assistance from a USPTO Customer Service  
Representative or access to the automated information system, call 800-786-  
9199 (IN USA OR CANADA) or 571-272-1000.

  
CARL LAYNO  
PRIMARY EXAMINER

  
Deborah L. Malamud  
Patent Examiner  
Art Unit 3766